

## UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,852	08/31/2001	Kevin P. Baker	P2548P1C13	8469
20.01	7590 02/11/2003 FER GILSON & LIONE	#	EXAM	INER
P.O. BOX 103 CHICAGO, IL	95		LOEB, BRONWEN	
			ART UNIT	PAPER NUMBER
			1636	7.
			DATE MAILED: 02/11/2003	3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary    Examiner		Application No.	Applicant(s)				
Brownen Mt. Loeb  The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Repty  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  THE MAILING DATE OF THIS COMMUNICATION.  If the period for reply specified above is less has afterly (30) days, a reply within the studient price in price price of the period for reply specified above is less has afterly (30) days, a reply within the studient price price of the period for reply specified above is less has afterly (30) days, a reply within the studient price price of the communication.  If the period for reply specified above is less has afterly (30) days, a reply within the studient price of the communication is the period of the communication. If the period for reply specified above is less than afterly (30) days, a replace the application to be communication. If the period for reply specified of the communication and the period of the communication. Period of the communication and the period of t		09/944,852	BAKER ET AL.				
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Elevations of time may be available under the provisions of 3 CFR 1-35(a). In an event, however, may a reply be limitly "feed after Sex (s) MONTH from the realing date of this communication.  It is genoted remay be available in site bits mit my Clay section will apply within the season or midly officed above the site bits mit my Clay section will apply available to reply within the set or extended period for reply will, by statute, cause the application is becomed the first own and part of the season or become 48-in/ONEO (50 to 3.C § 1-33).  Any reply recorded by the Office state than these mortes after the mailing date of this communication, event at timely filed, may reduce any search particle than a season or become 48-in/ONEO (50 to 3.C § 1-33).  Any reply recorded by the Office state than these mortes after the mailing date of this communication, event at timely filed, may reduce any search particle particle than the production of the mailing date of this communication, event at timely filed, may reduce any closed in accordance with the practice under Ex particle Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 22-27 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) 22-27 is/are pending in the application.  4a) Of the above claim(s) is/are eloved.  6) Claim(s) 22-27 is/are eloved.  6) Claim(s) are subject to restriction and/or election requirement.  Application Papers  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on 31 August 2001 is/are: a) Cacepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) The proposed drawing correction filed on is a subject to restriction in the data of the cation.  12) The oath or declaration is objected to by the Examiner.  Priority unde	Office Action Summary	Examiner	Art Unit				
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THE MAILING DATE OF THIS COMMUNICATION.  Extension for the may be availated under the provious of 3 °CFR 1 136(a). In no event, however, may a reply be timely filled after 5X (5) MCN1145 from the mailing date of this communication of 3 °CFR 1 136(a). In no event, however, may a reply be timely filled after 5X (5) MCN1145 from the mailing date of this communication of 15 °CFR 1 136(a). In the communication of 15 °CFR 1 136(a). The communication of 15 °CFR 1 136(a) and 15 °CFR 1 136(a). The communication of 15 °CFR 1 136(a) and 15 °CFR 1 136(a). The communication of 15 °CFR 1 136(a) and 15 °CFR 1 136(a). The communication of 15 °CFR 1 136(a) and 15 °CFR 1 136(a). The communication of 15 °CFR 1 136(a) and 15 °CFR 1 136(a). The communication of 15 °CFR 1 136(a) and 15 °CFR 1 136(a). The communication of 15 °CFR 1 136(a). This action is FINAL.  1)							
1)  Responsive to communication(s) filed on 31 August 2001 and 05 September 2002 .  2a) This action is FINAL. 2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 22-27 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 22-27 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.  Application Papers  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on 31 August 2001 is/are: a) accepted or b) objected to by the Examiner.  Application Papers  9) The specification is objected to by the Examiner.  10) The proposed drawing correction filed on is approved b) disapproved by the Examiner.  11) The proposed drawing correction filed on is approved by the Examiner.  12 proved, corrected drawings are required in reply to this Office action.  12 The cath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13 Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some to None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received.  14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 120 and/or 121.  Attachment(e)  Notice of References Cited (PTO-892)  Notice of Informal Patent Application (PTO-152)	A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any						
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Continuation of Attachment(s) 6). Other: information regarding Copy of Papers Originally Filed.

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## **DETAILED ACTION**

This action is in response to the preliminary amendments filed 31 August 2001 and 5 September 2002. The 31 August 2001 amendment cancelled claims 1-21 and provided new claims 22-27. The 5 September 2002 amendment amended the related applications statement in the specification.

Claims 22-27 are pending.

## Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 22-27 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 22-27 are drawn to an antibody which binds to the polypeptide shown in Figure 32 (SEQ ID No. 83; PRO361). The specification states that uses for anti-PRO antibodies include administration for treatment of various diseases, diagnostic assays or affinity purification of PRO proteins (pp. 88-89). The specification identifies PRO361 as a possible mucin and/or chitinase and that it may be associated with cancer, plant pathogenesis or receptor functions (p. 59, lines 1-4). The specification teaches that

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PRO361 is significantly expressed in lung, brain, kidney and liver (p. 142, Table 24, DNA45410-1250). The specification does not teach any specific cancer or disorder associated with PRO361 such that the antibodies against PRO361 could be used for diagnosis or for treatment. While PRO361 has biological activity in inhibiting proliferation of stimulated T-lymphocytes (p. 141, Example 34), there is no teaching what antibody against PRO361 could be used for in this respect. In the absence of such information, one skilled in the art has no guidance as to how to use the antibodies against PRO361 and it would require undue experimentation to determine how to use an antibody to the polypeptide of SEQ ID No. 83.

- 3. The following is a quotation of the second paragraph of 35 U.S.C. §112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 22-27 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 27 are vague and indefinite as claim 22 recites an antibody that bind to the polypeptide of SEQ ID No. 83 while claim 27 recites an antibody that binds specifically to the polypeptide of SEQ ID No. 83. Absent a specific definition, it is unclear what the difference between these two claims is and what subject matter each claim is meant to encompass given that antibody binding is determined by variable regions structure and is a specific reaction. Thus the metes and bounds of the claims cannot be determined.

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## Conclusion

Claims 22-27 are rejected.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the

examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding

is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D. **Patent Examiner** Art Unit 1636

February 10, 2003

**REMY YUCEL, PH.D** SUPERVISORY PATENT EXAMINER **TECHNOLOGY CENTER 1600** 

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